In mid-December the United States Congress passed, and, on December 20, 2018, the President signed the 2018 Farm Bill. By far the most noteworthy aspects of the bill relate to cannabis and hemp. Under the Controlled Substances Act (CSA,) marijuana is a Schedule I controlled substance like heroin. The problem is marijuana is defined as cannabis and cannabis covers the marijuana cultivar and the hemp cultivar. The Farm Bill removed hemp from the CSA as long as it contains less than 0.3 percent THC, the psychoactive component. This quick study looks at what industry can and cannot do in the wake of the legislation.

The new law expands the scope of options for the hemp industry. Hemp cultivation is now more permissible as opposed to the conditions under the previous law, which permitted only pilot programs on a limited scale. The legislation permits the movement across state lines for commercial and other reasons.

At the same time, the law is not free of restrictions. Any hemp product containing more than 0.3 percent THC will be treated as a Schedule I controlled substance, and thus illegal. The regulation of hemp production will be a shared enterprise involving the federal government and the state governments. The USDA must approve any state plan to license and regulate hemp (Section 10113). Where the states do not have or plan to have a hemp program, USDA will work with manufacturers to admit them into a federal program. The law lays out other violations in addition to the THC limit, including cultivating without a license. Other sections of the bill facilitate protection of hemp research (Section 7605).

Hemp will be treated like other agricultural commodities, which is an important element of the legislation. Even with the restrictions, hemp is now a crop like any other. This means that hemp farmers will be able to avail themselves of the protections of the Federal Crop Insurance Act that pertain to crop losses.

Cannabidiol (CBD), a derivative of cannabis, and especially the hemp cultivar, is now regulated in a more permissive fashion, but only under specified circumstances. Section 12619 removes hemp-derived products from Schedule I drugs, as noted above. However, any cannabinoid that is extracted from hemp will be legal only if the hemp is produced consistent with the provisions of the new law (less than 0.3% THC) and other state and federal regulations. All cannabis research projects must use research-grade cannabis from the Marijuana Program at the University of Mississippi School of Pharmacy’s National Center for Natural Products Research. That may raise issues given that hemp-sourced CBD should no longer be a scheduled drug and a company should not be required to use only the University of Mississippi research grade cannabis for research.

State marijuana programs remain federally illegal, despite the large number of states that have legalized medical marijuana and the few that have legalized recreational marijuana. This will complicate compliance with the law. In the end, there will be more legal CBD, if derived from hemp. That said, not all CBD programs will fall under the ambit of the new law. For example the FDA has made it clear that it will not tolerate the use of CBD in dietary supplements. Since the FDA has approved CBD as a drug for child epilepsy, all CBD products are now considered drugs with requirements such as clinical trials. To emphasize its position, the FDA issued several warning letters to supplement manufacturers who used...
CBD in their products. The following is an example of one of those letters: https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583192.htm

This has not stopped other industry actors from jumping into the market. The following is one of three Generally Regarded as Safe (GRAS) notices submitted to the FDA for CBD which found hempseed oil and two other products from Canada safe: https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM625546.pdf

Finally, it is still not certain if use of CBD in non-edibles, such as topical use, is condoned by the FDA in spite of a 2003 DEA regulation permitting such use. It should be noted that U.S. Customs follows the DEA rule for importation of topical products. Notwithstanding that the FDA has not taken a position on hemp products in cosmetics, any complaint by the FDA on the use of CBD or hemp oil in cosmetics, places the burden of proof on the FDA to prove that the product is injurious to the user. Furthermore cosmetic products are sold based on claims made by the company. These claims govern how the FDA will look at the product and thus may affect whether or not the FDA raises any issues.

In conclusion, the new law introduces changes that broaden the use of hemp and make CBD legal under certain conditions. That does not mean that all hemp is legal or that all products containing CBD can be sold.

Much is left unresolved which awaits FDA and DEA input at some point in the not too distant future. However there will continue to be questions without clear answers for some time to come. Further complicating the situation is the fact, as noted above, that more than 30 states have approved some form of marijuana use. It is also not certain how each state will treat hemp-derived CBDs. Without some clarity from the relevant governments and agencies, guidance on the production and marketing of cannabis derived products remains complicated and tortuous until the federal government and states reach some agreement on the legal and regulatory status of cannabis and its derivative products.

Clearly, this debate is in its early stages. From the initial impressions, industry is prepared to challenge FDA’s position at a minimum on CBD containing edible products. Until the FDA issues definitive regulations, ambiguity will continue in an industry that is expected to grow into the tens of billions of dollars over the next three years.

For more information on the matters discussed in this Locke Lord QuickStudy, please contact the authors.

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